

§ 725.422

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(5) *Sequences for toxins affecting membrane function.*

Sequence Source	Toxin Name
<i>Bacillus anthracis</i>	Edema factor (Factors I II); Lethal factor (Factors II III)
<i>Bacillus cereus</i>	Enterotoxin (diarrheagenic toxin, mouse lethal factor)
<i>Bordetella pertussis</i>	Adenylate cyclase (Heat-labile factor); Pertussigen (pertussis toxin, islet activating factor, histamine sensitizing factor, lymphocytosis promoting factor)
<i>Clostridium botulinum</i>	C2 toxin
<i>Clostridium difficile</i>	Enterotoxin (toxin A)
<i>Clostridium perfringens</i>	Beta-toxin; Delta-toxin
<i>Escherichia coli</i> & other Enterobacteriaceae spp.	Heat-labile enterotoxins (LT); Heat-stable enterotoxins (STa, ST1 subtypes ST1a ST1b; also STb, STII)
<i>Legionella pneumophila</i>	Cytolysin
<i>Vibrio cholerae</i> & <i>Vibrio mimicus</i>	Cholera toxin (cholera toxin)

(6) *Sequences that affect membrane integrity.*

Sequence Source	Toxin Name
<i>Clostridium bifementans</i> & other <i>Clostridium</i> spp	Lecithinase
<i>Clostridium perfringens</i>	Alpha-toxin (phospholipase C, lecithinase); Enterotoxin
<i>Corynebacterium pyogenes</i> & other <i>Corynebacterium</i> spp.	Cytolysin (phospholipase C), Ovis toxin (sphingomyelinase D)
<i>Staphylococcus aureus</i>	Beta-lysin (beta toxin)

(7) *Sequences that are general cytotoxins.*

Sequence Source	Toxin Name
<i>Adenia digitata</i>	Modeccin
<i>Aeromonas hydrophila</i>	Aerolysin (beta-lysin, cytotoxic lysin)
<i>Clostridium difficile</i>	Cytotoxin (toxin B)
<i>Clostridium perfringens</i>	Beta-toxin; Epsilon-toxin; Kappa-toxin
<i>Escherichia coli</i> & other Enterobacteriaceae spp.	Cytotoxin (Shiga-like toxin, Vero cell toxin)
<i>Pseudomonas aeruginosa</i>	Proteases
<i>Staphylococcus aureus</i>	Gamma lysin (Gamma toxin); Enterotoxins (SEA, SEB, SEC, SED SEE); Pyrogenic exotoxins A B; Toxic shock syndrome toxins (TSST-1)
<i>Staphylococcus aureus</i> & <i>Pseudomonas aeruginosa</i>	Leucocidin (leukocidin, cytotoxin)
<i>Streptococcus pyogenes</i>	Streptolysin S (SLS); Erythrogenic toxins (scarlet fever toxins, pyrogenic exotoxins)
<i>Yersinia enterocolitica</i>	Heat-stable enterotoxins (ST)

§ 725.422 Physical containment and control technologies.

The manufacturer must meet all of the following criteria for physical containment and control technologies for

any facility in which the new microorganism will be used for a Tier I exemption; these criteria also serve as guidance for a Tier II exemption.

(a) Use a structure that is designed and operated to contain the new microorganism.

(b) Control access to the structure.

(c) Provide written, published, and implemented procedures for the safety of personnel and control of hygiene.

(d) Use inactivation procedures demonstrated and documented to be effective against the new microorganism contained in liquid and solid wastes prior to disposal of the wastes. The inactivation procedures must reduce viable microbial populations by at least 6 logs in liquid and solid wastes.

(e) Use features known to be effective in minimizing viable microbial populations in aerosols and exhaust gases released from the structure, and document use of such features.

(f) Use systems for controlling dissemination of the new microorganism through other routes, and document use of such features.

(g) Have in place emergency clean-up procedures.

§ 725.424 Requirements for the Tier I exemption.

(a) *Conditions of exemption.* The manufacture or import of a new microorganism for commercial purposes is not subject to review under this part if all of the following conditions are met for all activities involving the new microorganism:

(1) The recipient microorganism is listed in and meets any requirements specified in § 725.420.

(2) The introduced genetic material meets the criteria under § 725.421.

(3) The physical containment and control technologies of any facility in which the microorganism will be manufactured, processed, or used meet the criteria under § 725.422.

(4) The manufacturer or importer submits a certification described in paragraph (b) of this section to EPA at least 10 days before commencing initial manufacture or import of a new microorganism derived from a recipient microorganism listed in § 725.420.